

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM)	NOTICE OF PUBLIC HEARING
37.104.601, 37.104.604, 37.104.606,)	ON PROPOSED AMENDMENT
37.104.610, and 37.104.615 pertaining)	
to automated external defibrillators)	

TO: All Interested Persons

1. On January 14, 2008, at 1:30 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room, 2401 Colonial Drive, Helena, Montana, to consider the proposed amendments of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process (including reasonable accommodations at the hearing site) or who need an alternative accessible format of this notice. If you need an accommodation, contact the department no later than 5:00 p.m. on January 7, 2008. Please contact Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951; telephone (406)444-9503; fax (406)444-9744; e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows. New matter is underlined. Matter to be deleted is interlined.

37.104.601 DEFINITIONS The following definitions apply to this chapter, in addition to the definitions contained in 50-6-501, MCA:

(1) "Automated external defibrillators (AED) training program" means a course of instruction approved by the department which provides the initial education in the use of the AED and which has requirements for continued assurance of the competency of individuals in using an AED.

(2) "CPR" means cardiopulmonary resuscitation.

(3) "Medical supervisor" means a physician, physician assistant, registered nurse, or nurse practitioner licensed in Montana who completes a training program provided by the department and who agrees to provide medical supervision to an approved AED program.

AUTH: 50-6-503, MCA

IMP: 50-6-501, MCA

37.104.604 WRITTEN PLAN (1) An entity wishing to use or allow the use of an AED shall develop, update as changes are made, and adhere to a written plan that:

(a) for a stationary location specifies the physical address where the AED will

be located;

(b) for a mobile location specifies the geographic area in which the AED will be used and specifies how the AED will be transported to the scene of a cardiac arrest;

(c) includes the names of the individuals currently authorized to use the AED;

(d) describes how the AED use will be coordinated with each licensed emergency medical service providing coverage in the area where the AED is located, including how emergency medical services will be activated every time that an AED is attached to a patient;

(e) specifies the name, telephone number(s), and address of the Montana licensed ~~physician~~ medical supervisor who will be providing medical supervision to the AED program and how the ~~physician~~ medical supervisor, or the ~~physician's~~ medical supervisor's designee, will supervise the AED program;

(f) specifies the name, telephone number(s) and address of the ~~physician's~~ medical supervisor's designee, if any, who will assist the ~~physician~~ medical supervisor in supervising the AED program;

(g) specifies the maintenance procedures for the AED, including how it will be maintained, tested, and operated according to the manufacturer's guidelines;

(h) requires that written or electronic records of all maintenance and testing performed on the AED be kept;

(i) describes the records that will be maintained by the program; and

(j) describes how the required reports of AED use will be made to the ~~physician supervising~~ medical supervisor of the AED program, or their designee, and to the department.

AUTH: 50-6-503, MCA

IMP: 50-6-501, 50-6-503, MCA

37.104.606 REPORTS (1) Every time an AED is attached to a patient, its use must be reported to the ~~supervising physician~~ medical supervisor or the ~~physician's~~ medical supervisor's designee and the report must include the information required by the ~~supervising physician~~ medical supervisor.

(2) Every time an AED is attached to a patient, the ~~supervising physician~~ medical supervisor or ~~their~~ the medical supervisor's designee shall provide the following information to the department on a form provided by the department:

(a) the name of the entity responsible for the AED;

(b) the name, address, and telephone number of the ~~supervising physician~~ medical supervisor;

(c) the date of the call;

(d) the age of the patient;

(e) the gender of the patient;

(f) location of the cardiac arrest;

(g) estimated time of the cardiac arrest;

(h) whether or not CPR was initiated prior to the application of the AED;

(i) whether or not the cardiac arrest was witnessed;

(j) the time the first shock was delivered to the patient;

(k) the total number of shocks ~~and joules~~ delivered;

(l) whether or not there was a pulse after the shocks and whether or not the pulse was sustained; and

(m) whether or not the patient was transported, and if so, the name of the transporting agency and the location to which the patient was transported.

AUTH: 50-6-503, MCA

IMP: 50-6-502, 50-6-503, MCA

37.104.610 TRAINING (1) In order to be authorized by an AED program plan to use an AED, an individual must:

(a) ~~have current training in adult~~ complete a cardiopulmonary resuscitation and AED training program that meets the standards of the American ~~h~~Heart ~~a~~Association and must renew this training at intervals not to exceed 2 two years;

(b) ~~complete one of the approved AED training programs listed in (2) below and renew the training at intervals not to exceed 2 years.~~

(2) ~~AED training programs developed by the following organizations are approved by the department:~~

(a) ~~American heart association;~~

(b) ~~American national red cross;~~

(c) ~~national safety council;~~

(d) ~~EMP international, inc.~~

AUTH: 50-6-503, MCA

IMP: 50-6-502, 50-6-503, MCA

37.104.615 MEDICAL PROTOCOL (1) A medical protocol for defibrillation use must be consistent with the ~~energy~~ requirements for defibrillation set out ~~on~~ pages 2211 through 2212 of in the "2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care, Recommendations of the 1992 National Conference" published in the Journal of the American Medical Association "Circulation", a journal of the American Heart Association, on October 28, 1992 November 29, 2005, Volume 268 112, Number 16 Issue 22 Supplement, and in, or with the 1998 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care.

(2) The department hereby adopts and incorporates by reference the ~~energy requirements~~ guidelines for defibrillation referred to in (1), which set standards for proper defibrillation. A copy of the documents referred to in (1) ~~above~~ may be obtained from the ~~Department of Public Health and Human Services, Health and Human Services Division, Emergency Medical Services and Injury Prevention Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951~~ American Heart Association at http://cir.ahajournals.org/content/vol112/22/22_suppl/.

AUTH: 50-6-503, MCA

IMP: 50-6-502, MCA

4. These changes to the existing rules are proposed to broaden the category of health professionals licensed in Montana who are qualified to be trained and

designated to supervise Automated External Defibrillator (AED) programs. Senate Bill 95 passed in the 2007 Montana legislative session (2007 Laws of Montana, Chapter 291) amended Title 50, chapter 6, part 5 of the Montana Code Annotated (MCA) in order to remove the requirement that a physician be the director of an AED program. The Legislature specifically provided that while medical oversight of an AED program is required, it need not be by a physician. The legislation also requires the department to set guidelines for the medical oversight of an AED program. The rules also update the training requirements that the department has set for persons who are trained to operate an AED.

ARM 37.104.601 Definitions

Senate Bill 95 changed the wording of "physician oversight" in 50-6-502 through 50-6-503, MCA to "medical oversight". These rules have been changed to reflect that. The term "Medical Supervisor" has been added to the definitions to identify the specific types of licensed healthcare professionals who are qualified to be trained and approved to provide medical oversight to AED programs.

ARM 37.104.604 Written Plan

The proposed changes to ARM 37.104.604 are to substitute "medical supervisor" for "physician" in the language in that rule that identifies the person who will be providing medical supervision to an AED program. This change is necessary to reflect the changes to the statutes. This rule is also changed to allow an AED program to maintain either written or electronic records of the maintenance and testing performed on the program's AED equipment.

ARM 37.104.606 Reports

There are two types of proposed changes to this rule. The first is changing references to the "supervising physician" to the "medical supervisor" to reflect the statutory changes. The second is to remove the requirement that AED programs report the number of joules of power delivered each time the AED was used. This change is based upon a change in technology since initial adoption of the rules. Previous American Heart Association (AHA) guidelines and the AEDs provided by vendors provided electrical shocks to a patient's heart at specific joules (e.g., 100, 200, and 300 joules). However, the advanced technology of many new AEDs provides shocks at various levels depending upon the technology being used, the patient's resistance to shock, and other factors. As such, the precise joules delivered to patients on many AEDs is unknown to the user. There is no regulatory reason to require reporting of that data. The requirement is therefore being removed.

ARM 104.610 Training

The proposed changes to this rule are made to allow an individual to be authorized by an AED program to use an AED if the individual has satisfactorily completed a

cardiopulmonary resuscitation (CPR) and AED program that meets the standards of the AHA. The existing rule had listed those organizations that provided training meeting those standards at the time the rule was originally adopted. However, there are numerous programs which provide cardiopulmonary resuscitation and defibrillation training and some of those programs change their names from time to time. Rather than attempting to maintain a current list of programs that provides training that meets the AHA standards, (1) of the rule as it is proposed to be amended specifies that any training that meets the standards of the AHA is acceptable.

ARM 37.104.615 Medical Protocol

The proposed changes to ARM 37.104.615 update the reference to the currently applicable set of guidelines for defibrillation adopted by and published by the American Heart Association. The guidelines which the department is adopting by reference are copyrighted and copies may be purchased through the journal cited in the rule or they are available at no cost through the web site link set out in the rule.

5. Interested persons may submit comments orally or in writing at the hearing. Written comments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951, no later than 5:00 p.m. on January 17, 2008. Comments may also be faxed to (406)444-9744 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

6. An electronic copy of this proposal notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of this notice conform to the official version of the notice as printed in the Montana Administrative Register, but advises all concerned persons that, in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. The web site may be unavailable at times, due to system maintenance or technical problems.

7. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by letter dated June 26, 2007, sent postage prepaid via USPS.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

/s/ Kim Kradolfer
Rule Reviewer

/s/ Joan Miles
Director, Public Health and
Human Services

Certified to the Secretary of State December 10, 2007.